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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,055	09/27/2005	Ralph Biemans	B45309	6847

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EXAMINER	
GANGLE, BRIAN J.	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
01/16/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/523,055	BIEMANS ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-17 and 45-46, drawn to methods of making a genetically engineered neisserial strain with an L2 immunotype of reduced phase variability by modifying the homopolymeric nucleotide tract of a phase-variable IgtA and/or IgtG LOS oligosaccharide synthesis gene.

Group II, claim(s) 1-4, 18-27, drawn to methods of making a genetically engineered neisserial strain with an L3 immunotype of reduced phase variability by modifying the homopolymeric nucleotide tract of a phase-variable IgtA and/or IgtG LOS oligosaccharide synthesis gene.

Group III, claim(s) 28, drawn to methods of making a genetically engineered neisserial strain with an L2 immunotype of reduced phase variability by modifying the homopolymeric nucleotide tract of a phase-variable IgtA and/or IgtG LOS oligosaccharide synthesis gene and downregulating the expression of the gene product of the IgtC gene.

Group IV, claim(s) 29, drawn to methods of making a genetically engineered neisserial strain with an L2 immunotype of reduced phase variability by modifying the homopolymeric nucleotide tract of a phase-variable IgtA and/or IgtG LOS oligosaccharide synthesis gene and downregulating the expression of the gene product of the IgtB or IgtE gene.

Group V, claim(s) 30, drawn to methods of making a genetically engineered neisserial strain with an L2 immunotype of reduced phase variability by modifying the homopolymeric nucleotide tract of a phase-variable IgtA and/or IgtG LOS oligosaccharide synthesis gene and either selecting a strain that is unable to synthesize capsular polysaccharide or downregulating the expression of the gene product of the saiD, ctrA, ctrB, ctrC, ctrD, synA, synB or synC gene.

Group VI, claim(s) 31, drawn to methods of making a genetically engineered neisserial strain with an L2 immunotype of reduced phase variability by modifying the homopolymeric nucleotide tract of a phase-variable IgtA and/or IgtG LOS oligosaccharide synthesis gene and downregulating the expression of the gene product of the msbB or htrB gene.

Group VII, claim(s) 1, 5, 32-33, 42, 45-48, and 52, drawn to methods of isolating L2 LOS.

Group VIII, claim(s) 34-36, 49-52, 54, 56, 58-60, drawn to methods of isolating neisserial blebs having an L2 LOS immunotype.

Group IX, claim(s) 1-2, 18, 37-38, and 43, drawn to methods of isolating L3 LOS.

Group X, claim(s) 39-41, 55, and 57, drawn to methods of isolating neisserial blebs having an L3 LOS immunotype.

Group XI, claim(s) 44 and 53, drawn to methods of making a multivalent immunogenic composition, comprising producing L2 LOS, producing isolated neisserial blebs having an L2 LOS immunotype, producing L3 LOS, producing isolated neisserial blebs having an L3 LOS immunotype, and mixing said components with a pharmaceutically acceptable excipient.

Gene Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on methods with patentably distinct combinations of genes. Each combination is patentably distinct because they are drawn to organisms with differing biochemical and immunological properties and a further restriction is applied to each Group.

If applicant elects one of Groups I-III or VII-XI, applicant must further elect IgtA and/or IgtG.

If applicant elects Group IV, applicant must further elect IgtA and/or IgtG, as well as IgtB or IgtE.

If applicant elects Group V, applicant must further elect IgtA and/or IgtG, as well as saiD, ctrA, ctrB, ctrC, ctrD, synA, synB or synC.

If applicant elects Group VI, applicant must further elect IgtA and/or IgtG, as well as msbB or htrB.

Applicant is advised that examination will be restricted to only the elected gene and this should not be construed as a species election.

It is noted that the claims of Group I are drawn (based on the inclusion of an LOS isolation step) so that it is not clear whether the claims are meant to be a method of making a genetically engineered neisserial strain or a method of isolating LOS. It is suggested that applicant proofread the claims and the claims will be examined in terms of the selected goal, as set forth in the Groups enumerated above.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-XI appears to be a genetically engineered strain of *Neisseria* with reduced phase variability, where the homopolymeric nucleotide tract of a phase-variable IgtA and/or IgtG LOS synthesis gene is modified to reender the expression of the gene less phase variable.

However, Gotschlich (J. Exp. Med., 180:2181-2190, 1994) disclose a strain of *Neisseria gonorrhoeae* where the homopolymeric tract of IgtA is deleted, rendering the strain less phase variable.

Therefore, the technical feature linking the inventions of Groups I-XI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the art.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571) 272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian Gangle
AU 1645

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SUPERVISORY PATENT EXAMINER
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